IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THERASENSE, INC. et al.,

Plaintiff,

v.

BECTON, DICKINSON et al.,

Defendant.
_____/

No. C04-02123 MJJ
No. C04-03327 MJJ
No. C04-03732 MJJ

ORDER DENYING BD/NOVA'S RENEWED MOTION FOR PARTIAL SUMMARY JUDGMENT

INTRODUCTION

Before the Court is Defendants Nova Biomedical Corporation's and Becton, Dickinson and Company's renewed Motion For Partial Summary Judgment That U.S. Patent No. 6,143,164 Is Invalid Under 35 U.S.C. § 102. (Docket No. 282.)

For the foregoing reasons, the Court **DENIES** the Motion.

FACTUAL BACKGROUND

Based on the record submitted by the parties, the Court finds the following facts to be undisputed for purposes of this Motion unless otherwise noted.

U.S. Patent No. 6,143,164 ("'164 Patent"), entitled "Small Volume In Vitro Analyte Sensor," issued on November 7, 2000. The "Field of the Invention" of the '164 Patent states that it relates to analytical sensors for the detection of bioanaltyes in a small sample size. ('164 Patent at 1:10-11.)

Claim 16 of the '164 Patent is the only independent claim asserted by Plaintiffs against the Defendants. It reads:

> 16. A method for determining a concentration of an analyte in body fluid of a patient, comprising the steps of:
> creating an unassisted flow of a body fluid from the patient;
> transporting a portion of the body fluid into an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid;
> holding the sample in a non-flowing manner within a sample chamber of the analyte sensor; and
> determining the concentration of the analyte in the body fluid from the portion of the body fluid transported into the analyte sensor.

('164 patent at 25:66-26:11.)

On August 31, 2006, this Court issued a claim construction order regarding the '164 patent. The Court construed three claim elements from claim 16 of the '164 patent as follows:

- The Court construed "unassisted flow" as "flow without the aid of any additional process or device to draw out more fluid than that which occurs once the flow has been initiated."
- The Court construed "an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid" as "a device designed to measure the concentration of an analyte given a sample of 500 nL or less of body fluid" (hereafter "Volume Limitation");
- The Court construed "holding the sample in a non-flowing manner within the sample chamber of the analyte sensor" as **"**the sample is not moving in the sample chamber during the measurement" (hereafter "Non-Flowing Limitation").

(Docket No. 209.)

In preliminary invalidity contentions served by Defendants on Abbott on July 16, 2005, Defendants contended that the '164 patent in invalid because, *inter alia*, it is anticipated by U.S. Patent No. 5,700,695, which is prior art. (Santarlas Decl., Exh. 7.) Around the same time, Defendants served Abbott with an interrogatory seeking Abbott's response to Defendants' invalidity contentions regarding the patents in suit. The interrogatory requested that to the extent Abbott disagreed with Defendants' invalidity contentions, Abbott should "state with particularity the bases for the disagreement including, but not limited to . . . an element-by-element comparison in claim chart form identifying which elements are not found in the prior art and all grounds tending to refute

such invalidity contention. . . ." (Santarlas Decl., Exh. 8.) After meet-and-confer discussions regarding the scope of this interrogatory, Abbott provided a response to the interrogatory on December 6, 2006 with respect to Defendants' contention that the '164 patent is anticipated by the '695 patent. (Santarlas Decl., Exh. 8.) Abbotts' response included several objections, including in relevant part that:

- "any issues raised by Defendants with respect to these defenses may depend upon the opinions of Defendants' experts which opinions shall be provided in an expert report",
- "some of Defendants' invalidity contentions do not identify a specific place in a prior art reference where a claim element is allegedly disclosed", and
- "[i]n some cases, inherent disclosure is alleged but insufficient explanation is provided as to why the element is inherently disclosed."

Abbott's response then included a claim chart, prefaced by the following language: "Below, Abbott identifies at least some elements that are missing from a single reference or combination or references. Abbott reserves the right to identify further claim elements that are not present in the reference or combination of references in question." The claim chart, as to independent claim 16, stated that Abbott's position as to the Volume Limitation was that "[t]his element is not taught by the '695 Patent." As to all other claim elements for independent claim 16, the corresponding box in the section entitled "Abbott's Response" was left blank.

On March 12, 2007, Abbott supplemented its interrogatory responses. Abbott's supplemental interrogatory response includes additional information not contained in its December 6, 2006 interrogatory responses regarding why Abbott believes that the Volume Limitation, as well as two other claim elements of the '164 patent, are not disclosed by the '695 patent.

Defendants now move for partial summary judgment, asserting that independent claim 16, as well as all dependent claims therefrom that are asserted in this case (claims 20, 22-24, 26-27, 36-38, and 40) are anticipated by the '695 patent.

LEGAL STANDARD

Federal Rule of Civil Procedure 56(c) authorizes summary judgment if there is no genuine

issue as to any material fact and the moving party is entitled to judgment as a matter of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The moving party bears the initial burden of demonstrating the basis for the motion and identifying the portions of the pleadings, depositions, answers to interrogatories, affidavits, and admissions on file that establish the absence of a triable issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party meets this initial burden, the burden then shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Celotex*, 477 U.S. at 324; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). The non-movant's bare assertions, standing alone, are insufficient to create a material issue of fact and defeat a motion for summary judgment. *Anderson*, 477 U.S. at 247-48. An issue of fact is material if, under the substantive law of the case, resolution of the factual dispute might affect the case's outcome. *Id.* at 248. Factual disputes are genuine if they "properly can be resolved in favor of either party." *Id.* at 250. Thus, a genuine issue for trial exists if the non-movant presents evidence from which a reasonable jury, viewing the evidence in the light most favorable to that party, could resolve the material issue in its favor. *Id*. However, "[i]f the [non-movant's] evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id*. at 249-50 (internal citations omitted).

Summary judgment is as appropriate in a patent case as it is in any other case. *C.R. Bard Inc. v. Advanced Cardiovascular Systems*, 911 F.2d 670, 672 (Fed. Cir. 1990). A patent is presumed valid. 35 U.S.C. § 282. The burden is on the party challenging the patent to show, by clear and convincing evidence, that the patent is invalid. *See Hybritech Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367 (Fed. Cir. 1986); *Invitrogen Corp. v. Clontech Laboratories, Inc*., 429 F.3d 1052, 1063 (Fed. Cir. 2005) (citing *Apotex USA, Inc. v. Merck & Co., Inc*., 254 F.3d 1031, 1036 (Fed. Cir. 2001)). Because this standard must be employed at the summary judgment stage just as it would be used at trial, Defendants have the burden of showing that there is an undisputed record from which a finder of fact would find by clear and convincing evidence that the '164 Patent is invalid. *Teton West Const. Inc. v. Two Rivers Const. Inc*., 961 F. Supp. 1422, 1426 (D. Idaho 1997).

A claim is anticipated under 35 U.S.C. § 102 only if each and every limitation of the claim is

disclosed in a single prior art reference. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). The prior art reference must disclose each element of the claimed invention sufficiently to place one of ordinary skill in the art in possession of it. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Accordingly, Defendants must establish by clear and convincing evidence, on the basis of undisputed facts, that every element of the asserted '164 patent claims is disclosed in the '695 patent. If there is a disputed issue of material fact as to whether even a single element is disclosed in the prior art, summary judgment as to that patent claim must be denied.

ANALYSIS

The Court first examines whether independent claim 16 of the '164 Patent is anticipated. If claim 16 is not anticipated by the '695 Patent, then none of the dependent claims asserted in this litigation are anticipated either. *Hartness Int'l v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1107-08 (Fed. Cir. 1987). To meet their burden of establishing anticipation, Defendants must establish that the '695 prior art reference discloses "each and every element of the claimed invention, arranged as in the claim." *Lindermann Maschinenfabrik GMBH v. Am. Hoist and Derrick Co.*, 730 F.2d 1452, 1458-59 (Fed. Cir. 1984).

Much of Defendant's motion papers, as well as Abbott's opposition, are directed to the Volume Limitation element. Defendants contend that certain disclosures in the '695 Patent, teaching that the "measurement chamber typically defines a volume of about 0.0002 ml to about 0.1 ml" ('695 Patent at 4:38-43), and further teaching that the invention can minimize the volume of the liquid sample used "[b]y drawing only enough of the liquid sample equal to the volume of measurement chamber 26" (id. at 5:26-38), disclose the Volume Limitation element. Abbott disagrees, contending the '695 Patent does not disclose a small enough sample size to read on the Volume Limitation element, and also does not teach how a sensor can be "configured and arranged" to measure the concentration of an analyte with 500 nL or less of body fluid.

However, even assuming, for purposes of analysis only, that the passages of the '695 Patent cited to by Defendants disclose the Volume Limitation, Defendants have not met their threshold burden of showing, by clear and convincing evidence, that the '695 Patent discloses each and every element of claim 16. Defendants rely on only two pieces of evidence in support of their motion: (1)

the '695 Patent itself (Santarlas Decl., Exh. 2); and (2) Abbott's December 6, 2006 interrogatory responses (Santarlas Decl., Exh. 8.) After reviewing this evidence, the Court concludes that it does not constitute clear and convincing proof that the '695 prior art reference discloses each and every element of the claimed invention, arranged as in the claim. *See Lindermann Maschinenfabrik*, 730 F.2d at 1458-59. For example, as discussed in more detail below, Defendants' evidence fails to establish, by clear and convincing proof, that the '695 Patent discloses the Non-Flowing Limitation in a manner that anticipates claim 16. This failure of proof is fatal to Defendants' motion.

A. Defendants' Evidence Fails To Establish That The Non-Flowing Limitation Is Disclosed By The '695 Patent.

After careful review of the evidence submitted by Defendants, the Court is unable to conclude, on a clear and convincing basis, that the '695 Patent discloses the Non-Flowing Limitation, *i.e.*, discloses that the sample is not moving in the sample chamber during the measurement.

The Court first turns to the content of the '695 Patent itself. Defendants contend, both in their motion papers and preliminary invalidity contentions, that the disclosure of stop junctions found at column 10, lines 24 through 30 of the '695 Patent disclose the Non-Flowing Limitation. This portion of the '695 Patent, describing the embodiment associated with Figure 12, reads:

> It is often desirable that the liquid sample not enter the thermal pressure chambers. This can be aided by using stop junctions, such as stop junctions 72, 72' at the junctions of slots 24g, 24g' and thermal pressure chambers 22g, 22g'. The stop junctions are configured to permit gas to pass relatively freely but to substantially prevent the passage of liquids.

As an initial matter, the passage cited to by Defendants says nothing about whether the body fluid sample found in the sample chamber is moving, or not moving, while the measurement is being taken. It discusses only the use of stop junctions to prevent the body fluid sample from moving beyond a certain point in the apparatus. No reasonable jury, from the disclosures contained in the '695 Patent alone, could draw the inference – and certainly not an inference that rises to the level of clear and convincing proof – that the use of a stop junction between the measurement chamber and the thermal pressure chamber necessarily prevents movement of the body fluid sample within the

measurement chamber during measurement.

Defendants present some limited attorney argument regarding the meaning of this passage in the '695 Patent, stating that "the '695 prior art patent specifically discloses stop junctions before and after the measurement chamber to trap sample within that chamber." (Reply at 7:1-2.) Such attorney argument, however, fails to satisfy Defendants' threshold burden of establishing, by clear and convincing proof, how one of ordinary skill in the art would understand the disclosure. Moreover, Defendants' characterization of the '695 Patent appears to be inconsistent with the specification. The relevant portion of the '695 Patent (column 10, lines 24-30 & Figure 12) discloses the use of stop junctions only ***after*** (but not before) the measurement chamber, and describe the purpose of said stop junctions solely as preventing liquid from entering the thermal pressure chambers, not immobilizing the fluid in the measurement chamber.

The only other evidence on which Defendants rely in an attempt to meet their burden is Abbott's December 6, 2006 interrogatory response, in which Abbott left blank the portion of its chart addressing the Non-Flowing Limitation of claim 16. (Santarlas Decl., Exh. 8.) Defendants contend that Abbott's interrogatory response constitutes a concession that the Non-Flowing Limitation is disclosed in the '695 Patent. The Court disagrees.

Interrogatory No. 18, as propounded by Defendants, requested that Abbott state whether it disagreed with Defendants' preliminary invalidity contentions, and the basis for any disagreement. (Santarlas Decl., Exh. 8.) However, with respect to this claim element, Defendants' preliminary invalidity contentions (which were served before the Court's claim construction order) asserted as follows:

> The apparatus uses a thermal pressure chamber to create a partial vacuum or positive pressure to move the liquid sample, typically blood, into a measurement chamber, however, it is often desirable to ensure that the liquid sample does not enter the thermal pressure chambers. This can be aided by using stop junctions to substantially prevent the passage of liquids. (1:52-55, 10:24-30).
>
> To the extent that holding a sample in a non-flowing manner means something other than having the sample flow out of the measurement zone, a person of ordinary skill in the art would have understood that this reference, in combination with at least Hodges '441, discloses this element. Motivation to combine is provided by at least the nature of the problem to be solved and the fact that these references are in the

> field of analyte sensors. Also, the desirability of the combination is suggested in the prior art by at least the disclosures cited herein.

(Santarlas Decl., Exh. 7.)

Accordingly, even Defendants' preliminary invalidity contentions appear to concede that, to the extent that the claim language "holding the sample in a non-flowing manner" is construed to mean "something other than having the sample flow out of the measurement zone", this claim element is not taught by the '695 Patent alone, but by the '695 Patent in combination with the Hodges '441 reference and/or other prior art references. This Court subsequently confirmed, in its claim construction order, that this claim element does indeed mean something other than preventing the sample from leaving the measurement zone – it requires that **"**the sample is not moving in the sample chamber during the measurement." (Docket No. 209.) Accordingly, Abbott's lack of a substantive response with respect to this claim element in its December 6, 2006 interrogatory response cannot fairly be read as a concession that this claim element is disclosed by the '695 Patent alone ***under the claim construction actually adopted by the Court***.

B. Even If The Non-Flowing Limitation Is Disclosed By The '695 Patent, Defendants Have Failed To Establish That The Disclosed Claim Elements In The Prior Art Reference Are Arranged As In Claim 16.

Even if the Court were to treat Abbott's December 6, 2006 as an outright concession that the Non-Flowing limitation is disclosed somewhere in the '695 Patent, Defendants still fail to meet their threshold burden of showing that the disclosed claim elements in the prior art reference could be arranged as in claim 16. At most, Abbott's interrogatory response would be as a general concession that the Non-Flowing Limitation is disclosed in connection with the Figure 12 embodiment described in the '695 Patent. It could not be read, however, as a concession that the Volume Limitation and Non-Flowing Limitation as disclosed in the '695 Patent could be arranged as in the asserted '164 claims.

To meet their burden of establishing anticipation, Defendants must establish that the '695 prior art reference discloses "each and every element of the claimed invention, arranged as in the claim." *Lindermann Maschinenfabrik*, 730 F.2d at 1458-59; *see also Advanced Cardiovascular Sys. v. Scimed Life Sys.*, 63 F. Supp. 2d 1064, 1073 (N.D. Cal. 1999) ("[a]nticipation cannot be proven by

cobbling together disparate elements in a prior art reference"). *Litecubes, L.L.C. v. Northern Light Prods., Inc.*, 2005 WL 2144574 at * 3-4 (E.D. Mo. 2005) (rejecting attempt to "pick and choose characteristics of the separate invention embodiments" in the reference").[1]

Here, there is particular reason to be concerned that Defendants may have combined disparate elements. The disclosures in the '695 Patent that Defendants contend teach the Volume Limitation and the Non-Flowing Limitation are associated with different embodiments of the '695 invention. The Figure 1 and 2 embodiment (to which Defendants point for disclosure of the Volume Limitation), which discloses a measurement chamber that can be as small as 0.0002 ml (200 nL), teaches that the invention can be performed with a liquid sample as small as volume of measurement chamber because:

> the user can then withdraw the sample port from the sample, agitate the sample if desired in the mixing chamber by thermal cycling of thermal pressure chamber 22 so that the liquid sample mixes with the reagent, and then move the sample liquid within the mixing chamber into measurement chamber 26 (thus drawing air through sample port 10). To ensure that enough sample has been obtained, fluid sample presence at a specific point in the flow path can be monitored; this can be done manually by a user or automatically by a suitable instrument. The fluid movement of the liquid sample can be controlled by precise control of the rate and amount of temperature drop in thermal pressure chamber 22.

('695 Patent at 5:38-50).

In contrast, the Figure 12 embodiment (to which Defendants point for disclosure of the Non-Flowing Limitation) is a sample collection apparatus that includes two thermal pressure chambers, each having a measurement chamber associated therewith, such that the body fluid sample entering through port 10g is split between two different passageways each leading to a different measurement chamber. ('695 Patent, Figure 12.) The body fluid sample in Figure 12 therefore does not appear to have a single "flow path", and must ultimately fill two measurement chambers simultaneously. This

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[1] Defendants cite an unpublished and non-precedential Federal Circuit case for the proposition that all elements of a claim need not be found in a single embodiment of the prior art reference. *See Beloit Corp. v. United States Int'l Trade Comm'n*, 845 F.2d 1033 (Table), 188 WL 7837 at *2 (Fed. Cir. 1988). It is true that a party asserting anticipation need not always establish that all elements are found in a single embodiment of the prior art reference. Where a prior art reference contains disparate elements in alternative embodiments that appear inconsistent with each other, however, the burden is on the party asserting anticipation to prove that the prior art reference discloses how all elements could be used together to one of ordinary skill in the art.

raises serious questions as to whether the thermal cycling technique described for the Figure 1 and 2 embodiment, which permits using a body fluid sample "equal to the volume of measurement chamber", could be utilized with the Figure 12 embodiment.[2]

Defendants have not adequately established that the two apparently disparate elements – the disclosure related to the Volume Limitation from the Figure 1 and 2 embodiment and the disclosure related to the Non-Flowing Limitation from the Figure 12 embodiment – are disclosed in a manner that they could be used together by one of ordinary skill in the art. Defendants have not submitted any expert testimony regarding the interrelationship between these two elements; indeed, no evidence submitted by Defendants addresses this issue. Accordingly, even assuming that the '695 Patent discloses both the Volume Limitation and the Non-Flowing Limitation in the manner contended by Defendants, a reasonable jury could not conclude that the '164 Patent is anticipated by the '695 prior art reference on the limited evidentiary record before this Court.[3]

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CONCLUSION

[2] For example, it is not established by clear and convincing evidence that a body fluid sample no larger that the sum of the volume of the two measurement chambers in the Figure 12 embodiment could be introduced through port 10g and successfully manipulated through thermal cycling of two different thermal pressure chambers such that the body fluid sample would split in the desired ratio between the two passageways and fill both measurement chambers.

[3] Expert testimony may not been necessary to establish anticipation in every instance, where the meaning of a prior art reference's disclosures to one of ordinary skill in the art are easily understandable to the fact-finder. But the situation here is not, as Defendants contend, one where "expert testimony will not be necessary because the technology will be easily understandable without the need for expert explanatory testimony." *Advanced Tech. Materials, Inc. v. Praxair, Inc.*, 2007 WL 1158103 at *2 (Fed. Cir. 2007). For the reasons discussed above, the disclosures in alternative embodiments found within the '695 patent, and the interrelationships between them, are not easily understandable to a layperson. *Cf. Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304 (Fed. Cir. 2002) ("Evidence of invalidity must be clear as well as convincing. Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference."); *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1151 (Fed. Cir. 2004) (reversing anticipation finding where party put reference into evidence but "otherwise failed to provide any testimony or other evidence that would demonstrate to the jury how that reference met the limitations of the claims").

Defendants have failed to meet their threshold burden of establishing anticipation by clear and convincing evidence. Accordingly, the Court **DENIES** the Motion.

IT IS SO ORDERED.

Dated: 7/10/2007

MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE